High-Tech Devices Help Ensure Product Safety

Federal regulators are testing new technologies to screen products for harmful substances in an effort to improve safety and cut inspection time from days or weeks to minutes.

An FDA investigator prepares a dietary supplement sample for analysis by an ion mobility spectrometer at the Port of Buffalo in Buffalo, N.Y. FDA is using high-tech devices to detect contamination of some products.

The Food and Drug Administration (FDA) says portable rapid spectroscopic technologies—which analyze the dispersion of an object's light to determine the object's chemical or molecular composition—may hold the key to a new era of product-safety screening.

These portable devices could significantly cut risks from contamination or counterfeiting of medicines, dietary supplements, cosmetics, and perhaps even foods, says FDA's Benjamin Westenberger, deputy director of the agency's Division of Pharmaceutical Analysis.

Sometimes, products are contaminated with other substances during the manufacturing process, mislabeled, or counterfeited and may contain different ingredients from those listed on the label. These new tools would allow investigators to screen imported products as they come into the country, moving additional safety controls further back in the supply chain. If the screening reveals a problem, a sample of the product would be sent to a field laboratory for further analysis, otherwise the product could be cleared to enter the United States.

Now, investigators from FDA's Office of Regulatory Affairs collect five or six samples from imported shipments at rail lines, warehouses, and ports of entry and send them for laboratory analysis. It can take more than a week to get the results.

Once they're approved for broad use, FDA chemist Selen Stromgren says the new portable devices will cut inspection time dramatically because investigators won't be tethered to a laboratory. Even so, test results from the portable devices will be treated as preliminary findings only. All positive findings and some negative findings will be confirmed in a laboratory, she says.

"The devices will allow us to review products in the field. In the future, many of these inspections may last no longer than an hour," says Stromgren, who's in FDA's Division of Field Science.

Increasing Inspections

David Elder, regional operations director for regulatory affairs, says FDA has a team of more than 2,000 scientifically trained specialists who conduct inspections and investigations, collect and analyze product samples, oversee recalls, take enforcement actions, and monitor regulated products coming into the U.S. This includes everything from food, drugs and vaccines for people and animals to cosmetics and medical devices.

All imports are electronically

screened by FDA personnel, and more than 100,000 laboratory analyses are performed each year on about 31,000 samples from imported products. From Oct. 1, 2009, to Sept. 30, 2010, FDA examined more than 210,000 imported products in the field and conducted at least 1,196 foreign inspections. In addition, FDA conducted more than 16,000 inspections on domestically produced products. Westenberger says the volume of drugs and other products imported into the U.S. has more than doubled in the past decade, challenging the capacity of the import-testing process used in most inspections.

Currently, FDA examines up to 2 percent of all regulated imports. But by using the new portable devices, the agency could boost its ability to test products before they reach consumers. Elder says FDA has trained investigators around the country to use the devices and has targeted specific products for screening.

FDA's Lucinda Buhse, director of the pharmaceutical analysis team, says FDA could greatly increase the percentage of regulated products tested.

The Technologies

FDA is testing a number of different types of portable scanning devices to detect chemicals. Each technology works to detect characteristics, or "signatures," of specific chemical components when product samples are exposed to particular types of light.

These technologies include:

- Raman spectroscopy, which uses a scatter of laser light from a sample to obtain a "fingerprint" that can identify the chemical composition of the sample. When the laser light scatters from a product sample, a fraction of the light is scattered in wavelengths that are slightly different from the original wavelength of the laser. Those slightly different wavelengths help analysts identify the chemical composition. FDA scientists have used the technology to detect diethylene glycol (DEG) in glycerin, a sweetener and thickener used in drug products. DEG, a poisonous chemical found in antifreeze, made news in 2007 when it was detected in imported toothpaste.
- Near-infrared (NIR) spectroscopy measures how a product sample absorbs NIR, a light that is invisible to the human eye. The chemical composition of a sample determines the wavelengths and amount of light it can absorb. This allows NIR spectroscopy to provide a "fingerprint" that can be used to identify the composition of the sample. FDA scientists have used the technology to detect DEG in propylene glycol—a liquid in food, drugs, and cosmetics—and melamine (a compound used to make plastics) in lactose, a sugar found in milk. In 2008, FDA found melamine in some imported baby formula, touching off a nationwide scare.
- Ion mobility spectrometry (IMS) IMS analyzes a sample's chemical composition, first by ionizing the molecules and then by measuring their unique movement within an electric field. It has been widely used for military and security purposes to detect explosives and illegal drugs. FDA has used the technology to detect the presence of sibutramine (Meridia)—a weight loss drug that is no longer distributed in the United States—in dietary supplements and the antidepressant Prozac, or fluoxetine hydrochloride, in herbal products.

Future Benefits

If these technologies are proven effective and put into regular use by FDA, Westenberger says they could revolutionize product inspection worldwide.

FDA could take the technology to other countries, not only to further improve the safety of imported foods and drugs that come into the United States, but to help other nations improve their safety programs.

"They could help us be more efficient in regard to time, manpower, and money. Westenberger says. "These devices could also help in the fight against counterfeit products; and they could help us avoid loss of life from contaminated products, whether on a local or catastrophic scale." FDA

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